

Developing Breakthrough Non-Surgical Therapies; Improving Patient Lives

November 2022 | Nasdaq: MDWD

### **Cautionary Note Regarding Forward-Looking Statements**

MediWound cautions you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties, and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "could," "may," or similar expressions. Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the European Medicines Agency or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future. These and other significant factors are discussed in areater detail in MediWound's annual report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 17, 2022, Quarterly Reports on Form 6-K and other filings with the SEC from timeto-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law

Trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of the Company. Certain data in this presentation, including the market research data contained on slides 4, 22, 23, 24 and 26, was obtained from various external sources, and neither the Company nor its affiliates, advisers or representatives has verified such data with independent sources. Accordingly, neither the Company nor any of its affiliates, advisers or representatives makes any representations as to the accuracy or completeness of that data or to update such data after the date of this presentation. Such data involves risks and uncertainties and is subject to change based on various factors.

NexoBrid development has been supported in part with federal funding from U.S. Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract numbers HHSO100201500035C and HHSO100201800023C. Contract number HHSO100201500035C provides funding and technical support for the pivotal U.S. Phase 3 clinical study (DETECT) and the marketing approval registration process for NexoBrid as well as its procurement and availability under the expanded access treatment protocol (NEXT) in the U.S. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in pediatric population, establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States.

We maintain our books and records in U.S. dollars and report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board. None of the consolidated financial statements incorporated by reference into this presentation were prepared in accordance with generally accepted accounting principles in the United States.

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Committed to innovation; developing breakthrough therapies, dedicated to improving patient care

# **Innovative Biotherapeutic Company**

#### Next generation non-surgical solutions for tissue repair and regeneration

#### Proprietary enzymatic technology platform

Clinically and commercially validated bioactive therapies; 100+ peer reviewed publications, 13 successful clinical studies, approved in 41 countries

#### **Diversified and differentiated portfolio**

Targeting unmet medical needs; multi-billion\$ addressable markets

#### Supported by strategic collaborations

BARDA, Vericel (US), and Kaken (Japan)

#### cGMP certified sterile manufacturing facility

Proven management team with vast pharmaceutical experience and extensive capabilities

Solid balance sheet; Strong investor base



### **Portfolio of Advanced Therapies**



#### **EscharEx**®

Pipeline

Bromelain-based mixture of enzymes extracted

from the pineapple stem

Next-gen enzymatic therapy for wound care\*\*

Indication: Debridement of chronic/hard-to-heal wounds
Classification: Biological drug candidate
Target users: Outpatient setting
Development status: 3 Phase II studies completed

#### TAM\* (U.S.): >\$2 billion

MW005 Biotherapy for non-melanoma skin cancers\*'

Indication: Treatment of non-melanoma actinic skin cancers

Classification: Biological drug candidate

Target users: Outpatient setting

Development status: Phase I/II study underway

TAM\* (U.S.): >\$1 billion



Commercial

**NexoBrid®** Disruptive therapy for burn care

Indication: Eschar removal of deep partial and full thickness burns

Classification: Orphan biological drug

Target users: Hospitalized patients

Substantial U.S. government support

**Development status:** EU and international market approvals; registration-stage in U.S.

TAM\* (U.S.): >\$200 million

\*TAM - targeted addressable market; source: Oliver Wyman market research \*\*Investigational Drug; not approved in any jurisdiction



MNPC005

### **Leadership Team**





Nachum (Homi) Shamir Chairman of the Board Ofer Gonen Chief Executive Officer



**Prof. Lior Rosenberg** Founder & Chief Medical Technology Officer



Dr. Ety Klinger Chief R&D Officer



**Tzvi Palash** Chief Operating Officer **Boaz Gur-Lavie** Chief Financial Officer



Dr. Robert J. Snyder Chief Medical Director EscharEx

Affiliations: *Luminex*. GIVEN° Kodak

Affiliations: gamida ell CACTUS I Affiliations:

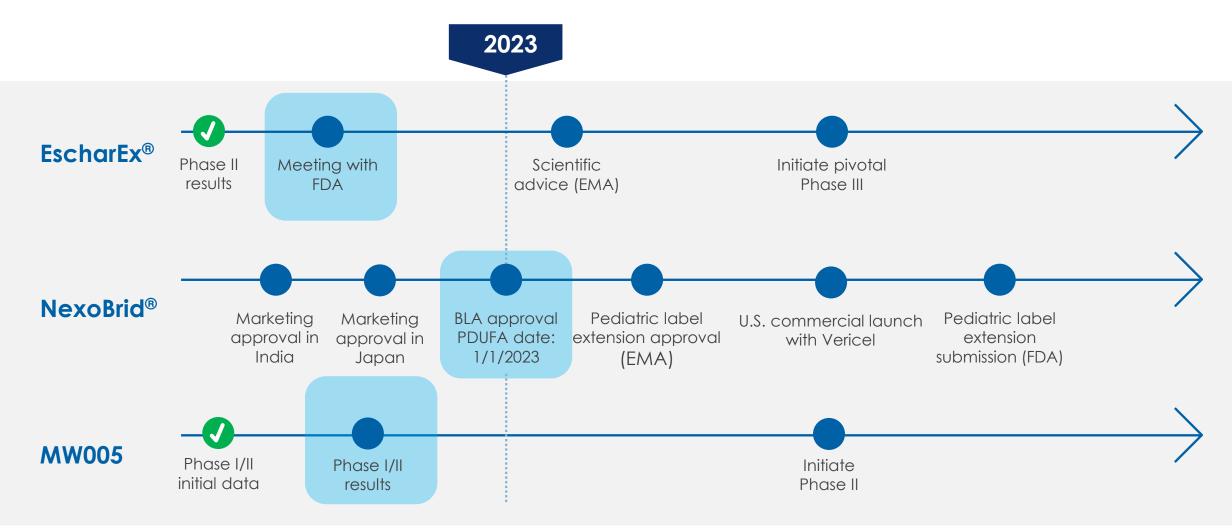
Affiliations: teva PROTEO LOGICS TEL AUIU UNIVERSITY Affiliations: gamida ell PROTALIX Biotherapeutics







### **Upcoming Milestones**





### **Financial Highlights**

	Balance Sheet	<ul> <li>\$17.6M in cash* as of September 30, 2022</li> <li>Additional \$17.2M raised in October 2022</li> <li>\$7.5M milestone payment upon BLA approval (PDUFA date Jan 2023)</li> </ul>	MDWD		
	Revenues	<ul> <li>1-9/2022 revenues of \$14.9M</li> <li>Expecting marketing approvals in Japan, India and U.S to support product revenues growth in 2023</li> </ul>	<b>Analysts:</b> Josh Jennings, MD, Cowen Jacob Hughes, Wells Fargo Francois Brisebois, Oppenheimer Swayampakula Ramakanth, PhD, HCW David Bouchey, Aegis		
ARABIT	Strategic U.S. partnerships	<ul> <li>Significant support by BARDA:</li> <li>Funding and technical support for NexoBrid's programs</li> <li>Procurement for U.S. emergency stockpile (\$16.5M)</li> <li>Commercial collaboration with Vericel</li> <li>DoD collaboration for NexoBrid military use</li> </ul>			







# NexoBrid®

**Disruptive Bioactive Therapy for Burn Care** 



### Early Eschar Removal is Critical First Step in Burn Care

#### **Eschar Removal**

- Prevents local infection and sepsis
- Avoids further deterioration and scarring
- Enables initiation of wound healing
- Allows visual assessment of wound bed, enabling an informed treatment plan



#### **Current Standard of Care**



#### Surgical eschar removal

- Tangential excision
- Dermabrasion, Hydro-jet

#### Significant limitations

- Traumatic & non-selective
- Loss of healthy tissue and blood
- Challenging in delicate areas
- Requires surgical team, OR resources



#### Non-surgical eschar removal

- Autolysis
- Enzymes, chemicals & biologics

#### Significant limitations

- Limited efficacy
- Increased eschar-related complications
- Multiple dressing changes

Clear unmet need for an early, effective and selective non-surgical debridement treatment for severe burns





NexoBrid®

Concentrate of proteolytic enzymes enriched in bromelain

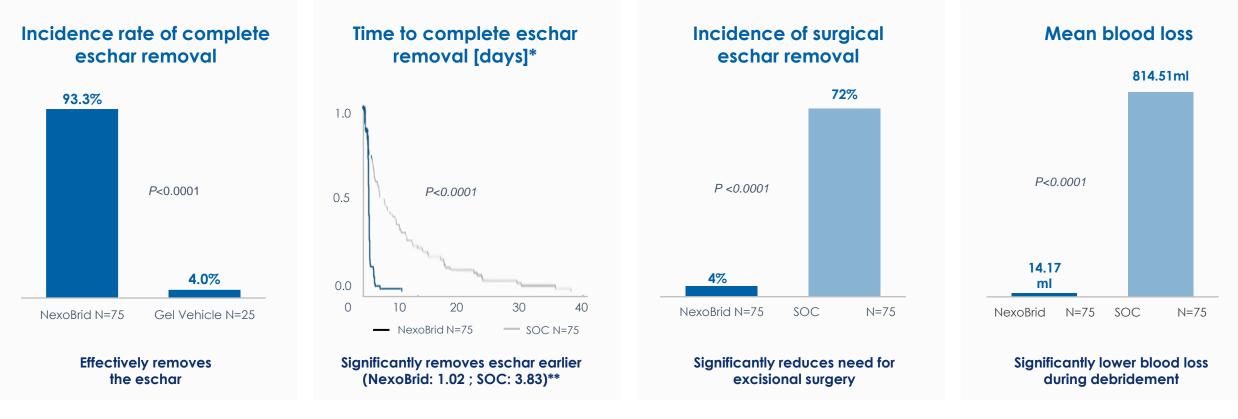
NexoBrid is indicated for removal of eschar with deeppartial and full-thickness thermal burns

- Orphan biological product
- Bromelain-based biological product containing a sterile mixture of proteolytic enzymes
- Easy-to-use, topical application at the patient's bedside
- Effectively and selectively removes burn eschar within 4 hours of a single application without harming surrounding viable tissue or blood loss
- Allows for early visual assessment of the wound
- Approved in 41 countries (EU and ROW); registration stage in the U.S. and Japan
- Significant IP protection: patent portfolio, orphan and biologic exclusivities in the U.S.





### NexoBrid Phase III – Safety & Efficacy are Well Demonstrated



- Non-inferiority established in time to complete wound closure
- No safety issues after 24 months follow-up
- Consistent with the European Phase III clinical trial, and with Phase III study in pediatric population

\*Kaplan-Meier analysis \*\*Estimated median time (days)



### **Commercial Strategy**

North	Commercial Collaboration	<ul> <li>Active commercial infrastructure targeting burn centers</li> <li>&gt;\$200M, addressable market in the U.S.*</li> <li>Pre-commercialization marketing and medical initiatives underway</li> </ul>
America	Government Contracts	<ul> <li>Awarded up to \$211M BARDA's contracts (thermal burns &amp; chemical burns)</li> <li>NexoBrid R&amp;D programs are fully funded</li> <li>Initial procurement valued \$16.5M; \$50M option for additional procurement</li> <li>DoD contract for field and military use</li> </ul>
EU	Direct Sales Force	<ul> <li>Presence in six key markets**</li> <li>Focus on leading burn centers - centers of excellence</li> <li>Distribution agreements in additional countries</li> </ul>
International markets	Local Distribution Partners	<ul> <li>Global expansion through distribution agreements</li> <li>Focus in LATAM, CEE, Asia-Pacific and GCC</li> <li>Procuring additional regional marketing approvals</li> <li>Distributor funds registration &amp; commercialization activities</li> </ul>

\* Based on commercial partner estimation and ABA fact sheet

\*\* DACH, U.K, Italy, Spain, Poland and Romania







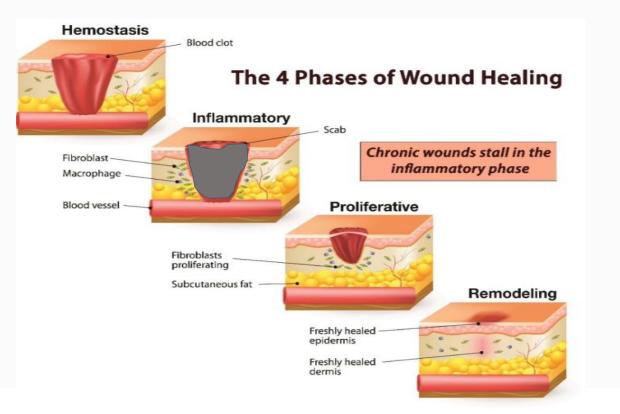
# EscharEx<sup>®</sup>

Next-Generation Enzymatic Debridement & Wound Bed Preparation Solution for Chronic Wounds



### **Debridement is the First Step in Chronic Wound Healing**

#### Debridement



#### **Current Standard of Care**



#### Sharp debridement (efficiency)

- Surgical, Sharp
- Ultrasonic, Versajet
- Larvae

#### Significant limitations

- Painful
- Requires anesthesia
- Bleeding risk
- Requires a trained specialist



#### Non-sharp debridement (tolerability)

- Enzymatic
- Autolysis

#### Significant limitations

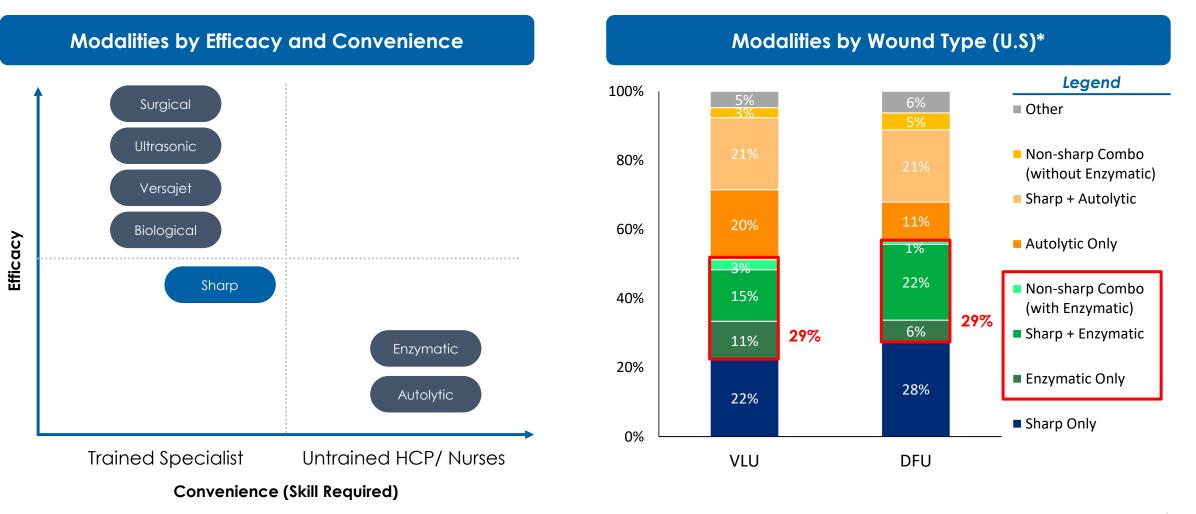
- Limited efficacy
- Multiple nurse/office visits for 6-8
   weeks

Significant Medical Need for Rapid and Effective Debriding in Outpatient Settings



### **Current Debridement Modalities**

Sharp is the current Standard-of-Care, but pain and need for skilled HCPs are significant drawbacks







# EscharEx

Next Generation Enzymatic Debridement Therapy

- Bromelain-based investigational biological product containing a sterile mixture of proteolytic enzymes
- Designed for outpatient setting
- Inline with current treatment workflows and reimbursement landscape
- Easy to use, high potency for once-a-day topical application
- Designed to debride chronic wounds in 4-6 applications
- Extended IP protection; regulatory exclusivity

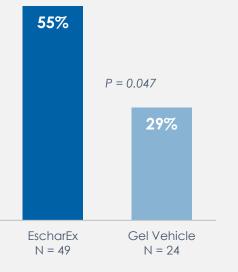




### Phase II Study in VLU, DFU and Post Trauma Wounds

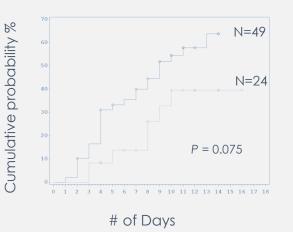
Conducted in Israel and Europe; 73 patients

Incidence of complete debridement\*



Significantly higher incidence of complete debridement

Time to complete debridement \*\*



Shorter time to achieve complete debridement

#### **Study Results**

- EscharEx had significantly higher incidence of complete debridement after up to 10 applications
- Complete debridement was achieved earlier in patients treated with EscharEx
- The effect was greater for VLUs and DFUs

#### No safety concerns

- EscharEx with different doses & dosing regiments was compared to Gel Vehicle
- No safety concerns were identified in all doses and dosing regiments
- No deleterious effect on wound healing was observed

#### >90% of the patients completed debridement with EscharEx within 7 days (4-5 applications)

\*w/i up to 10 daily applications \*\*Kaplan-Meier survival analysis with log rank p-value



### **Phase II Study in VLU Patients**

Conducted mainly in US; examined an improved formulation of EscharEx; 120 patients

Study Objectives:	Study Design
To assess safety and efficacy of EscharEx	
compared to Gel Vehicle (placebo control) and non-surgical SOC*	Endpoints

- A multicenter (USA, Israel and Switzerland), prospective randomized assessor blinded study for treatment of venous leg ulcers (VLUs)
- Sample size: 120 VLU patients (EscharEx; Gel Vehicle; non-surgical SOC)
- Treatment: up to 8 applications of 24 hrs each

#### Primary

Incidence of complete debridement of non-viable tissue vs. Gel Vehicle

#### Secondary endpoints

Time to complete debridement; pain & wound area reduction; granulation tissue; wound QoL

#### Safety

Local and systemic safety & tolerability; incidence & time to wound closure



\*Non-surgical standard of care - enzymatic or autolytic debridement

### EscharEx Phase II – Safety & Efficacy are Well Demonstrated

#### Primary Endpoint met with Statistical Significance



Higher incidence of complete debridement\*

#### **Primary Endpoint**

Patients treated with EscharEx demonstrated a significantly higher incidence of complete
 debridement compared with patients treated with Gel Vehicle

#### EscharEx vs. Gel Vehicle

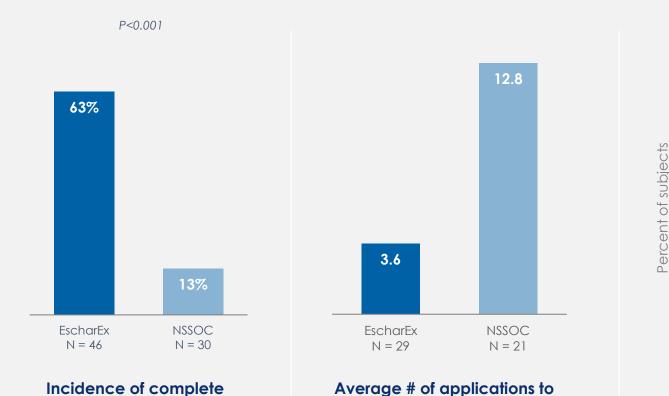
- Statistically significant higher incidence of at least 75% granulation tissue
- Comparable reduction in pain, reduction in wound area, and in wound QoL
- Shorter time to achieve complete debridement with fewer applications

#### No safety concerns

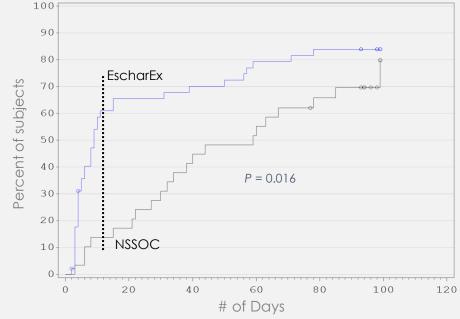
- No deleterious effect on wound healing
- Non-inferiority established for incidence of complete wound closure, and for time to complete wound closure



### EscharEx vs. Non-Surgical SOC



Time to achieve complete debridement\*\*



Estimated median time to achieve complete debridement: EscharEx- 9 days vs. NSSOC - 59 days

achieve complete debridement

\*w/i up to 8 daily applications \*\*Kaplan-Meier survival analysis with log rank p-value

debridement\*



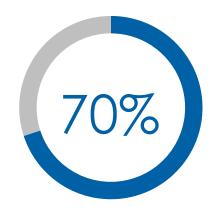
### Phase II Pharmacology Study

Conducted in US; demonstrates additional advantages of EscharEx; 12 patients

Study Objectives: To evaluate the clinical performance and	Study Design	<ul> <li>3 U.S. clinical sites</li> <li>Sample size: 12 patients with VLUs or DFUs</li> <li>Prospective, open-label, single-arm, pharmacology study</li> </ul>			
pharmacological effects of EscharEx in the debridement of lower leg ulcers	Data Collection	Clinical performance Safety and efficacy	<b>Effect on biofilm</b> Reduction of biofilm	<b>Bacterial</b> <b>burden</b> Reduction of bacterial load	Wound progression Bio-markers (e.g. cytokines, MMPs)



### Phase II Pharmacology Results



Patients achieved complete debridement within up-to 8 applications



Decrease in wound size by the end of a two-week follow-up



Biofilm was reduced substantially for all patients positive for biofilm at baseline

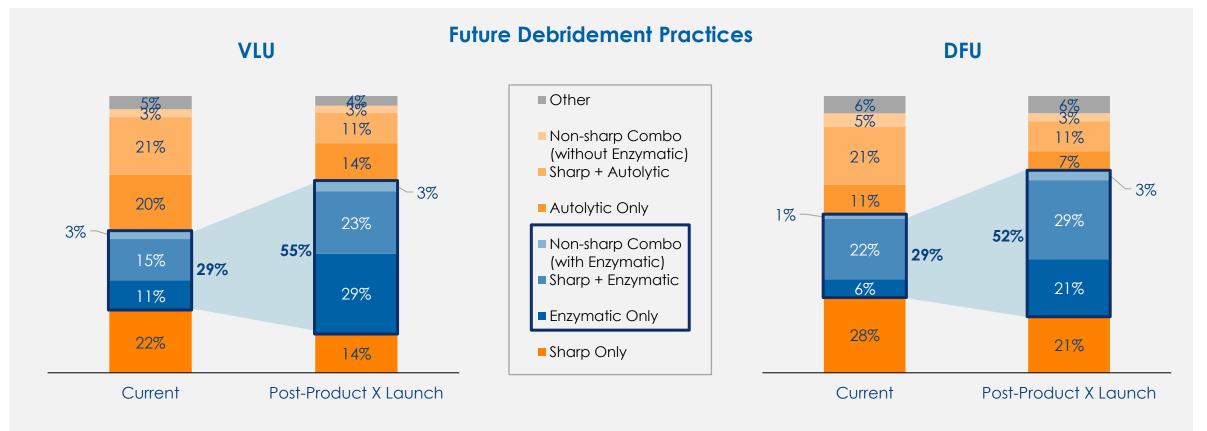
#### On average,

- Complete debridement was achieved after 3.9 applications of EscharEx
- Significant debridement of wounds during the treatment period (84.9% of NVT removed)
- Seven patients with positive red fluorescence at baseline showed reduction from 1.69 cm<sup>2</sup> pre-treatment to 0.60 cm<sup>2</sup> post treatment

EscharEx demonstrated safe, effective and rapid debridement in VLUs and DFUs; Reduced wound size, biofilm and bacterial burden



### EscharEx to Significantly Expand Use of Enzymatic Debridement



EscharEx anticipated to draw share from all other debridement modalities

MediWound 23

Source: OW Primary Research (6/2022)

### U.S. Market Opportunity

~2.1M VLU and DFU patients eligible for debridement each year

55% - 70% Wounds debrided

#### 43%

Debrided by enzymatic methods Research indicates that EscharEx can expand enzymatic market

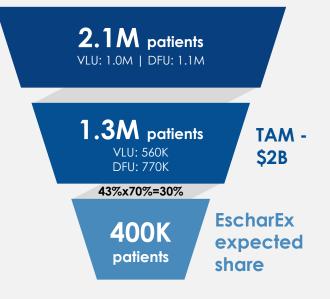
#### 70%

Anticipated EscharEx market share based on superiority 5 Years-to-Peak Share

# CoT: \$1,500 (base) / \$1,800 (upside) / \$1,200 (downside)

CoT\*: based on 5 applications on average @ \$300 per application

#### 2022 Epidemiology Estimate



Feedback supports potential to extrapolate beyond initial indication given similarities of debridement approaches



### **Commercial Strategy**

🔊 Target

#### Site of care:

- Hospital-based outpatient
   department
- Wound care clinics
- Skilled nursing facilities
- Home care

#### Key clinicians:

- Vascular specialists
- Plastic surgeons
- Podiatrists
- Primary care physicians

### Pricing

- Current enzymatic debridement average cost of treatment estimated at \$1,600-\$2,000
- Pricing to reflect cost saving



- Existing reimbursement codes for enzymatic debridement
- Hospital Outpatient Prospective Payment System (OPPS) code 97602:

"Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic abrasion), including topical applications(s), wound assessment, and instruction(s) for ongoing care, per session."





# **MW005**

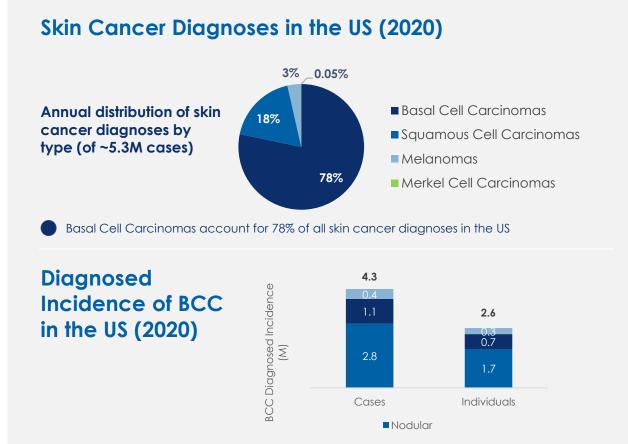
### Biotherapy for Non-Melanoma Skin Cancer

- Bromelain-based investigational biological product containing a sterile mixture of proteolytic enzymes
- Designed for outpatient setting
- Easy to use, high potency, for once-a-day topical application
- Designed to destroy superficially invasive and nodular types BCCs in 5-7 applications
- Published Proof of Concept: 7 successfully treated BCCs were destroyed in 2-6 applications, minimal scars, no recurrance for 18 months





### Non-Melanoma Skin Cancer Market Opportunity



NCCN estimates that the annual incidence of NMSC has increased by 4-8% each year since the 1960s

- Basal Cell Carcinomas (BCC) is the most diagnosed skin cancer in the US
- 4.3M cases are comprised of ~2.6M individual patients, as BCC can recur after primary treatment of the tumor, and patients may also receive treatment for multiple cases/ lesions
  - Surgery is the most frequently used and effective treatment for BCC, but treatments vary based on cancer type, size, depth, and location
  - ~1.1M cases diagnosed in the US each year for superficial BCC; topical treatments with limitations (Imiquimod & 5-FU) are indicated for superficial BCC only



### MW005 Ongoing Phase I/II Study

An open-label, single-arm Phase I/II study	Study Objectives	<ul> <li>Assess the safety and tolerability of MW005 in the treatment of Basal Cell Carcinoma</li> </ul>	
Conducted in US	Study Design	<ul><li>2 cohorts of up to 16 patients each</li><li>Nodular and superficial BCC</li></ul>	
Data readout expected in H2 2022	Data Collection	PrimaryExploratorySafety systemic & local AEs,Percentage of target lesionsVS, pain assessments,(i.e. patients) with completetolerabilityclinical & histological clearance	

• Initial data shows MW005 to be safe and well tolerated, with a majority of the patients achieving complete clinical & histological clearance of their target lesions



# Why MediWound?

### **EscharEx**®

# NexoBrid®

MW005

### **Our Focus: The Game Changer**

Sets a new bar for efficacy; a billion \$ market opportunity De-risked: based on a validated technology Superior to non-surgical standard of care Pursuing an accelerated regulatory pathway Executing a global approach Exploring strategic alternatives

### Profitable and Validated

PDUFA date 1/1/2023 Once approved expected to generate meaningful revenues BARDA, Vericel, DoD and Kaken collaborations EMA Pediatric label extension expected in Q1/2023

### **Great Potential**

Positive initial data readout





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